

### Remarks

Applicants wish to thank Examiner Pohnert for the useful telephonic interview of December 2, 2009 and for reviewing the claim proposal transmitted by Applicants. In the interview, Examiner Pohnert indicated that Applicants' November 25, 2009 Amendment was improper because the November 4, 2009 Amendments to the specification and claims had already been entered. That is, the Amendment submitted by Applicants on November 25, 2009 improperly presupposed that the November 4, 2009 amendments had not been entered. Thus, the November 25, 2009 Amendment was not compliant with USPTO rules, and therefore has not been entered.

Applicants apologize for this oversight, and thank Examiner Pohnert for the November 17, 2009 Advisory Action entering the Amendments to the claims and specification from Applicants' November 4, 2009 submission. As the November 4, 2009 amendments to the specification have been entered and are believed to properly effect incorporation by reference of GenBank Accession X04500., please withdraw the outstanding new matter rejection.

Applicants thank Examiner Pohnert for the helpful telephone discussion held December 2, 2009, in which the instant claim amendments were discussed. The Examiner and Applicants' representative agreed that the newly presented claims, which recite predisposition to serum cholesterol elevation of greater than 239 mg/dL, overcome the rejections under 35 U.S.C. §112.

Support for the new claims may be found throughout the disclosure, e.g., on page 12, which discusses Applicants' findings that individuals homozygous for the thymine (T) allele at position (-511) and the cytosine (C) allele at position (-31) of the IL-1 $\beta$  gene promoter may be predisposed to larger increases in total blood cholesterol levels upon treatment with rapamycin regimens, and on page 19, which provides Table 10 having an odds ratio showing that patients treated with everolimus are 7.23 times more likely to have an increase in total blood cholesterol levels to greater than 239 mg/dl if they contain a C at position -31 of the IL-1  $\beta$  gene promoter. Please withdraw the outstanding enablement-based rejection of the pending claims.

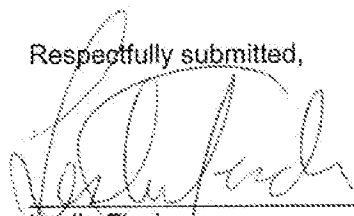
## CONCLUSION

In light of the above amendments, observations and remarks, Applicants respectfully submit that the presently claimed invention satisfies 35 U.S.C. §112, and is neither disclosed nor suggested by any art of record. Accordingly, reconsideration and allowance of all claims in this application is earnestly solicited.

Applicants' undersigned attorney may be reached in our New Jersey office by telephone at (862) 778-9308. All correspondence should continue to be directed to our below-listed address.

Novartis Pharmaceuticals Corp.  
Patents Pharma  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-9308

Respectfully submitted,

  
\_\_\_\_\_  
Leslie Fischer  
Attorney for Applicants  
Reg. No. 58,393

Date: 12/3/09